Attorney Docket No.: 24222-X3
Serial No.: 09/982,093
Inventor: Cherukuri
Filing Date: 10/19/2001

REMARKS

Claims 1-24 are pending. Claims 8-24 were withdrawn from consideration. Claims 1-7 were rejected under 35 USC 103(a) as allegedly being unpatentable over Jerussi, et al (US 6,197,828). The Office alleged that "the difference between Jerussi and the claims is one of size and differences in size would not support the patentability of applicant's caplet over the caplet of the prior art" and requested comparable data to show that caplets recited in the claims provide unusual results.

Applicants respectfully disagree with the Office's position. The Office has not established its prima facie case under 35 USC 103(a). The Office has not shown that the Jerussi Patent provides any motivation to one of skill in the art to use Jerussi's disclosure and make the necessary modifications to arrive at the applicant's invention. The Office simply asserts that it is within ordinary skill in the art to make modifications, without any substantiation. Applicant respectfully traverses the Office's position.

However, applicant hereby provides unexpected results that the Office has requested. By providing these results, applicant does not waive his right to contest the above position that the Office has failed to make its prima facie case. These results are provided

primarily to advance prosecution.

To that end, applicant hereby submits a Rule 132 Declaration describing the experiments undertaken to show the unexpected results.

Applicant has attempted to follow the Jerussi disclosure to make a controlled release venlafaxine product that exceeds about 7mm in size and compare its dissolution profile with that made using the applicant's disclosure. Please see paragraphs 6 through __ of the declaration.

As provided in the Declaration, applicant tried but was unable to make a tablet of 9mm size by following the Jerussi disclosure of columns 26 and 27. The dry blend powder could not be compressed and remained as a powder. Applicant then conducted three additional experiments to improve upon the Jerussi disclosure so that a pharmaceutically acceptable tablet of 9mm size could be produced. In experiment 2, applicant tried to granulate the product in an effort to improve compressibility. Again, applicant could not compress the granules into a tablet. In Experiment 3, applicant used talc to improve compressibility and hardness. However, the product was still unsatisfactory. Applicant then conducted Experiment 4 whereby more talc was used and this time, the product was compressible and of suitable hardness. Applicant then studied

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Jerussi's disclosure and that is outside the claim, did not exhibit a controlled release profile. Practically 90% or more of the drug was released within the first hour.

Applicant respectfully submits that Jerussi does not suggest the claimed invention. One of ordinary skill in the art would not take the Jerussi disclosure and make the necessary modifications to arrive at the applicant's invention. There is simply no motivation or suggestion for that. Even if there were to be some suggestion, there is no reasonable expectation of success that Jerussi's disclosure would provide a controlled release product. Clearly, from the applicant's Declaration, the Jerussi disclosure leads to an immediate release product, not a controlled release product as claimed by the applicant.

In summary, applicant respectfully submits that the outstanding 35 U.S.C 103(a) rejection be withdrawn and the pending claims be allowed.

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